

CRITERIA FOR PRIOR AUTHORIZATION

Kymriah® (tisagenlecleucel)

PROVIDER GROUP Professional**MANUAL GUIDELINES** The following drug requires prior authorization:
tisagenlecleucel (Kymriah®)**CRITERIA FOR APPROVAL** (must meet all of the following):

- Patient must have a diagnosis of relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL)
- Documentation of CD19 tumor expression
- The patient must have acute lymphoblastic leukemia that is refractory or in second or later relapse defined as the following:
 - Second or greater bone marrow relapse,OR
 - Not achieving a complete response after 2 cycles of standard chemotherapy
- If disease is Philadelphia chromosome positive (must meet the following):
 - The patient must have experienced treatment failure with 2 tyrosine kinase inhibitors (TKI) (e.g. imatinib, dasatinib, nilotinib, bosutinib, ponatinib) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced; (Prior authorization is required for selected TKI)
- Patient must be less than or equal to 25 years of age
- Must be prescribed by, or in consultation with, an oncologist or hematologist
- Patient must not have any active infection or active inflammatory process
- Patient must meet the following (if applicable):
 - Females: not be pregnant (verified negative pregnancy test prior to initiating treatment for those of reproductive potential) and be advised to not become pregnant during treatment
- The patient must be receiving the medication from a healthcare facility that is enrolled and in compliance with the Kymriah REMS requirements
- Patient has not received prior CAR-T therapy
- Dose must not exceed the recommended dose based on weight (below)
 - For patients 50 kg or less: administer 0.2 to 5.0 x 10⁶ chimeric antigen receptor (CAR)-positive viable T cells per kg body weight
 - For patients weighing greater than 50 kg: administer 0.1 to 2.5 x 10⁸ CAR-positive viable T cells per kg body weight

LENGTH OF APPROVAL: 1 YEAR

DRUG UTILIZATION REVIEW COMMITTEE CHAIR

PHARMACY PROGRAM MANAGER
DIVISION OF HEALTH CARE FINANCE
KANSAS DEPARTMENT OF HEALTH AND ENVIRONMENT

DATE

DATE